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JUL 06 2004
PATENT & TRADEMARK OFFICE

Attorney's Docket No. 6858P001X4 Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Stephen J. Brown

Application No.: 09/237,194

Filed: January 26, 1999

For: REMOTE HEALTH-MONITORING SYSTEM WITH NETWORKED SERVER AND HEALTH CARE PROFESSIONAL

Examiner: Kalinowski, Alexander G.

Art Group: 3626

RECEIVED
JUL 8 2004
GROUP 3600

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION/AFFIDAVIT OF PRIOR INVENTION IN THE UNITED STATES TO OVERCOME CITED PATENT OR PUBLICATION (37 C.F.R. § 1.131)

Dear Commissioner:

1. My name is Stephen J. Brown and I am the sole inventor of the subject matter claimed in patent application USSN 09/237,194 ("this patent application").

2. This is an affidavit under 37 CFR § 1.131 showing conception of the invention claimed in this patent application prior to the effective date of the reference cited by the Examiner. Conception of the invention was coupled with due diligence from prior to the effective date of the earliest application from which the present application claims priority (USSN 07/977,323, filed November 17, 1992).

3. The effective date of US patent 5,390, 238 (Kirk et al.) is the date that it is effective as a reference under 35 U.S.C. 102(e), i.e., June 15, 1992.

4. **I invented the invention in this patent application before June 15, 1992.**

   a. As evidence, I attach, as Exhibit 1, a copy of a March 2, 1992 fax letter from me to Boerhringer Mannheim GmbH.

   b. The second paragraph of this fax describes the elements of Figure 1 of this patent application. For example, the data management unit 10 is mentioned, so too are the hand held unit 12 (video game), modem (52), communications with doctors at 56, and the fact that the doctor and patient are remote from each other (implicit in the words "home system which connects to the doctor").

   c. This system had been developed by the time the fax had been sent (as evidenced by the words "have developed") and, as illustrated by the fax itself, was in a form appropriate to discuss with potential buyers.

5. **This prior invention was coupled with due diligence until the application was filed.**

   a. On or before August 13, 1992 enough design work had been done to produce a schematic, a list of features and a hardware "wish list" for the invention (see Exhibit 2).

   b. Also, by August 13, 1992 enough work had been done to hire a hardware engineer as a consultant to implement the invention (see the NDA of Craig Nelson and handwritten notes, attached as Exhibit 3).

   c. On or before August 14, 1992 a basic hardware design (see 2-page Exhibit 4) existed.

   d. All the documents in Exhibits 2 to 4 were sent on August 14, 1992 to an attorney for the purposes of preparing a patent application (see Jack Thornton's fax cover sheet to Richard Black attached a Exhibit 5).

   e. By September 3, 1992 attorney Jim Anable had been instructed to prepare the patent application (see Exhibit 6).

   f. A retainer of $6,000 was paid to the attorney's firm, Christensen O'Conner, et al on or around September 15, 1992 (see Exhibit 7).

g. Attorney Anable sent a first draft of this patent application to me for review as inventor on October, 2 1992 (see Exhibit 8).

h. On that same day, I faxed to the attorney a drawing of the invention that should have been in the application (see Exhibit 9).

i. Christensen O'Conner, et al continued to work on the application during the months of October and November until the effective filing date of this application. (See Christensen O'Conner, et al billings attached as xhibit 10)

j. The application was filed on November 17, 1992 as USSN 07/977,323, an application from which this application 09/237, 194 claims priority.

6. Based on the above and as is evident from the attached exhibits, the invention and reduction to practice of the subject matter described in this application was prior to the effective date of US patent 5,390, 238 (Kirk et al.) i.e., June 15, 1992.

7. As the below signed inventor, I, Stephen J. Brown, hereby declare that all statements herein are of my own knowledge and are true and that all statements made on information and belief are believed to be true; and further that these statements are made knowing that willful false statements and the like are punishable by fine or imprisonment, or both under § 1001 of Title 18 of the United States Code, and such willful and false statements may jeopardize the validity of the application or any patent issuing on the application.

Very Truly yours,

Dated: June 28, 2004

Full Legal Name: Stephen J. Brown
Citizenship: U.S.A.
Address: 3324 Woodside Road, Woodside, California

Exhibit 1

Date March 2, 1992

To Dr. Norbert Jersch
Dr. Thomas Keiser
Central Marketing Patient Systems
Boehringer Mannheim GmbH
fax (011 49 621) 759 4179

From Steve Brown
Raya Systems
Mountain View, CA
fax (415) 949 3935

re Camit, Diabcare

Thank you for the order for Camit 2.5. We accept the conditions, except that we would like to start development on April 6, rather than March 1. As I discussed with Hartmut, it makes more sense for us start closer to the time when a prototype will be available. I want to devote continuous attention to the project until completion, rather than doing some development now and then waiting for the prototype EL.

With regard to Diabcare, I would like to have a new agreement confirming our fax transmittals of the last two months.

I have developed an interface for the Camit EL to a Nintendo video game machine, and am producing a data management program for the Super Nintendo Entertainment System. In the United States, Nintendo video game computers are in 40 million homes. They are inexpensive and attach to television sets. Raya Systems is licensed by Nintendo to produce such a product, and I hope to discuss the possibilities with BM USA. Can you tell me who to contact there? This could be an ideal platform for a home system which connects to the doctor system (Camit) via modem.

Sincerely,

Steve Brown

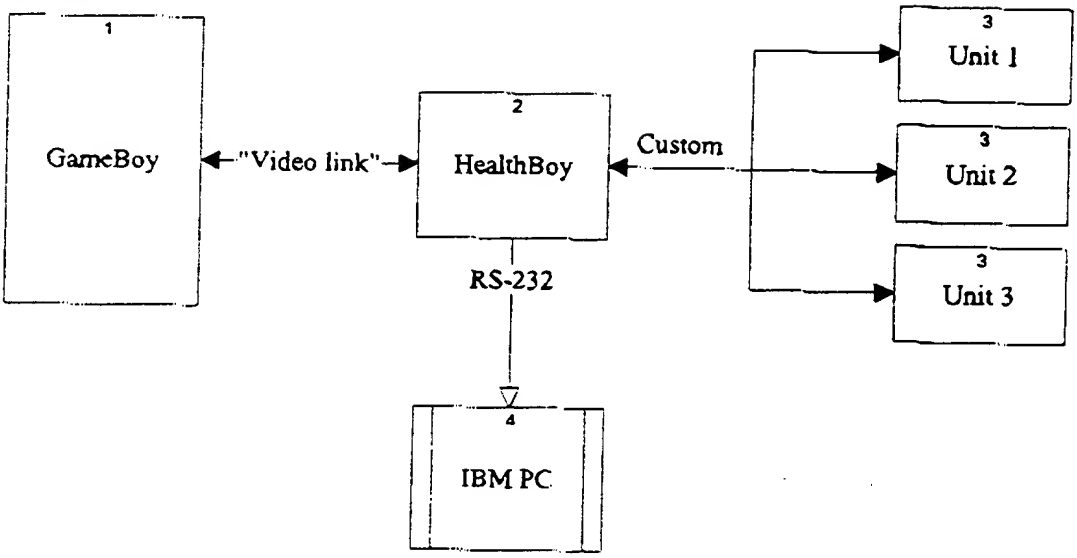
rayasystems

HealthBoy Project

TopChart

Thursday, August 13, 1992

11:46 AM



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HealthBoy features:

- *Communicate to GameBoy via serial "Video-Link" (multi-player) cable*
- *Communicate to multiple external devices (e.g. diabetes blood-sugar meter) via custom hookup*
- *Dump data to external computers (e.g. IBM PC) via RS-232 (9-pin connector)*
- *Clock/Calendar capability for time/date stamp of samples*
- *Internal battery backed-up RAM for storage of samples*
- *Low-power microprocessor*
- *Input connectors designed to be "user stupid"/hard to damage*
- *GameBoy cartridges for each external device for display of data*

Hardware wish list:

- *Microprocessor with multiple interrupt levels*
- *Hardware-driven communications with GameBoy with buffer*
- *Automatic RS-232 buffer*
- *Hardware-driven communications with external devices with buffer*
- *Large amount of RAM for long-term storage of samples*

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Exhibit 3

[redacted]
rayasystems

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Non-Disclosure Agreement

This agreement is made to be effective the 13th day of August, 1992 by and between Craig Nelson and Raya Systems, Inc., 2570 West El Camino Real, Suite 309, Mountain View, CA 94040, hereinafter referred to as "PARTIES."

The "PARTIES" agree that, with respect to any confidential information disclosed by one PARTY to the other, both PARTIES will apply and honor the mutual covenants and promises described below:

(1) "Confidential Information" shall be any and all information which is in fact confidential and proprietary to the disclosing PARTY and which the disclosing PARTY designates as confidential at the time such disclosure is made;

(2) The non-disclosing PARTY shall not disclose or cause to be disclosed, in whole or in part, any such Confidential Information to any third party without the prior written consent of the disclosing PARTY, except where:

(a) at the time of disclosure, the Information is publicly known, or was already known (as evidenced by documents) by the non-disclosing PARTY, or

(b) after disclosure to a PARTY, such information becomes publicly known through no fault of the PARTIES, or

(c) disclosure is required by law or governmental agency or any subdivision thereof, or

(d) seven (7) years have elapsed from the date upon which disclosure is made;

(3) In the event that either of the PARTIES breaches this agreement, the breaching PARTY shall be liable for any and all losses resulting from said breach which are incurred by the non-breaching PARTY.

8/13/92
Date

By: Craig Nelson

8/13/92
Date

RAYA SYSTEMS, INC.

By: Jack Thornton
Director of Product Development

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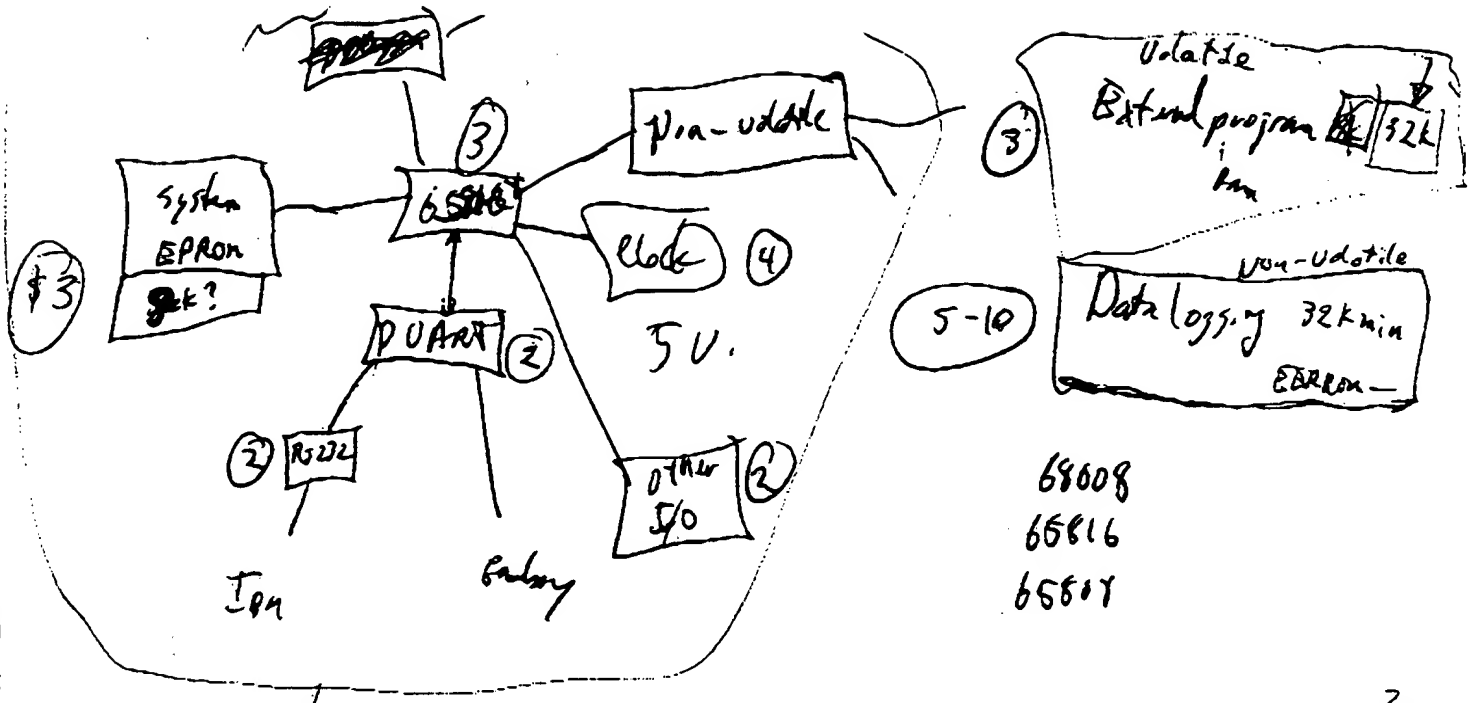


2 @ 100ma @ 5V.

30

Sense

Logger

4

max standby 1ma

100

30ma ← 100hrs

~3-4.5

Lawyer neck slack

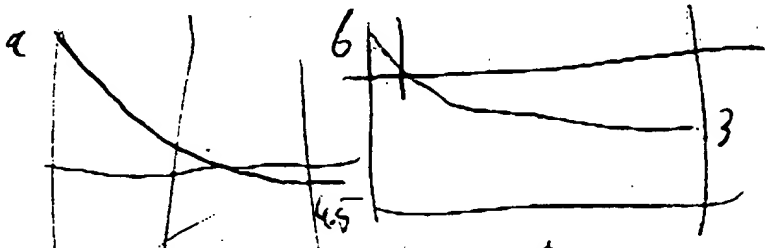
3 - AA ~ 3 Ahr.

1) full on
2) Standby
3) Off

Lyve 6AA — 500ma — 5hrs

management consulting ??

$ 3B



6

assembly ~ $1 unit

PCB ~ $1

plastic tooling — $ plus 20K

4 months

maybe 6 months

1 — Circuit design - 1 month design - $50 hr

1 — PCB layout - 2 weeks; Electronics - bad cost max $35

prototype - 1 month $30 hr

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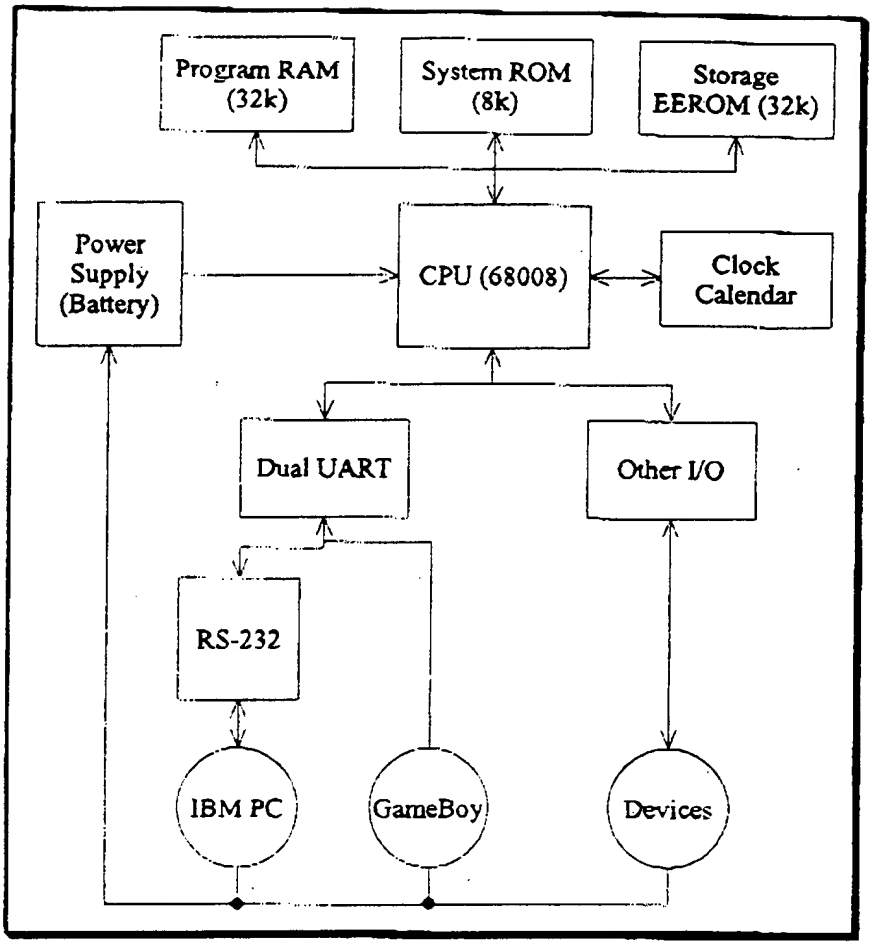

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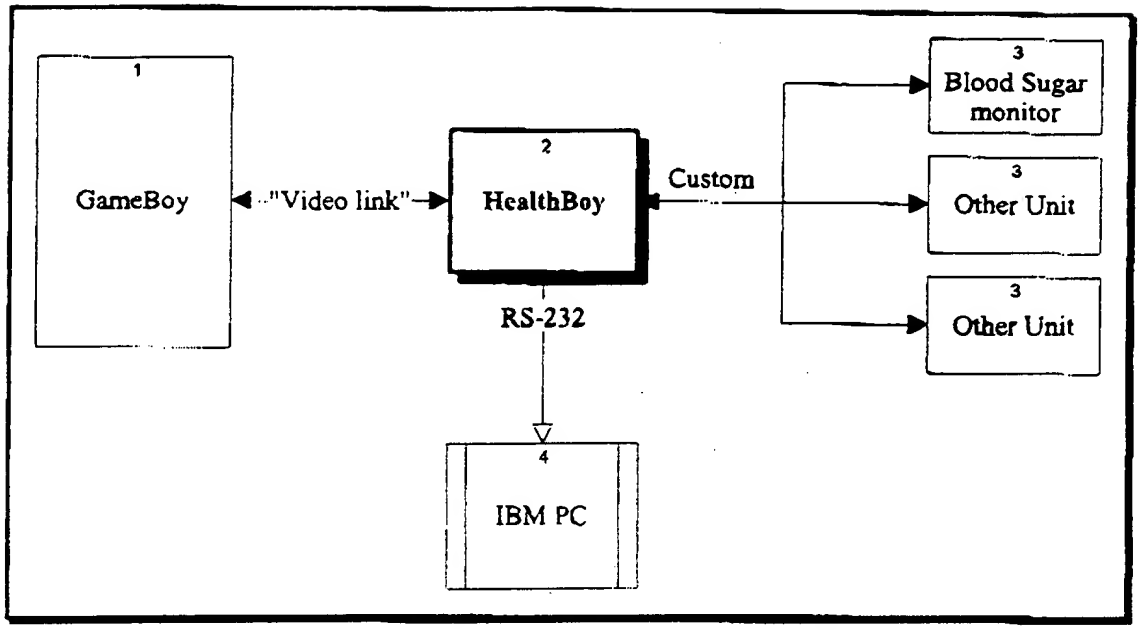
Development Cost (estimates)

Description	Units	Unit type	Rate	% use	Brdn Rate	Cost
Hardware design/test	6	weeks	$2,000.00	100%	100%	$12,000.00
Hardware prototyping	4	weeks	$800.00	100%	100%	$3,200.00
Circuit board design	2	weeks	$1,200.00	100%	100%	$2,400.00
Plastic design & development	4	months				$20,000.00
Software design	4	weeks	$1,000.00	100%	125%	$5,000.00
Software implement/test	6	weeks	$1,000.00	100%	125%	$7,500.00
Management	14	weeks	$1,084.62	10%	125%	$1,898.08
Clerical	14	weeks	$538.46	5%	125%	$471.15
Photocopy/Supplies	14	weeks	$10.00	100%	100%	$140.00
Telephone	14	weeks	$10.00	100%	100%	$140.00
Shipping						$300.00
GameBoy Develop. system						$13,000.00
IBM PC System						$2,500.00
Estimated costs						$68,549.23
Reserve (15%)						$10,282.38
Total development budget						$78,831.62

Note:
Another option is to build our own custom chip to perform most of the functions of the separate parts specified in the design.
Advantages:

Functional design / features



Basic hardware design

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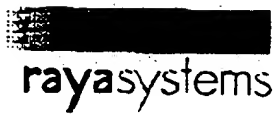
Exhibit 5

FAX LETTER



Raya Systems, Inc.
2570 West El Camino Real, Suite 309, Mountain View, California 94040
Phone (415) 949-3933 Fax (415) 949-3935

TO:	Richard T. Black
COMPANY:	Oles, Morrison & Rinker
FAX NUMBER:	(206) 682-6234
FROM:	Jack Thornton
DATE:	August 14, 1992
RE:	HealthBoy project - potential patent application
NUMBER OF PAGES:	7, including this one
CC:	Steve Brown

CONFIDENTIAL

I have been instructed by Steve Brown to forward notes about the HealthBoy project to you for the purposes of a possible patent application. I met with a hardware engineer yesterday, and based on that information I have a very preliminary design of the central module with cost estimates. Included in this fax are my notes, the engineer's (Craig Nelson's) handwritten notes, and the non-disclosure agreement signed by Craig.

As more information is developed, I will be forwarding it to you.

If you have any questions, please feel free to give me a call.

RECEIVED
8:15 am
AUG 14 1992
OLES, MORRISON & RINKER

Sincerely,

Jack Thornton
Director of Product Development
Educational Software

CONFIDENTIAL

Exhibit 6

OLES, MORRISON & RINKER
LAWYERS

3300 COLUMBIA CENTER
701 FIFTH AVENUE
SEATTLE, WASHINGTON 98104-7007
(206) 623-3427
TELECOPIER: (206) 682-6234

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BRUCE T. RINKER
DAVID C. STEWART
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THEODORE L. PREG
WILLIAM G. JEFFERY
ROBERT J. BURKE
DAVID H. KARLEN

BRADLEY L. POWELL
DOUGLAS S. OLES
PETER N. RALSTON
MICHELE M. SALES
MARK F. O'DONNELL
JOHN LUKJANOWICZ
DAVID R. TRACHTENBERG
JAMES F. NAGLE
KRIS J. SUNDBERG

RICHARD T. BLACK
TIM W. DORE
MICHAEL H. FERRING
HARLAN M. HATFIELD
T. DANIEL HEFFERNAN
EVALYN K. HODGES
JON G. HONGLADAROM
JOHN F. JENKEL

TRAEGER MACHETANZ
GLENN R. NELSON
TODD M. NELSON
JOHN V. OHNSTAD, JR.
BRIAN E. ONORATO
J. CRAIG RUSK
ROBERT W. SARGEANT

STUART G. OLES
OF COUNSEL

GERALD DE GARMO
(1903-1988)

September 3, 1992

VIA FAX

Mr. Stephen Brown
Raya Systems, Inc.
2570 West El Camino Real, Suite 309
Mt. View, CA 94040

RE: Patent Application

Dear Steve:

As per your instructions, we have authorized Jim Anable to begin work on your application. He and his office should be contacting you frequently in the next several weeks, and it is important that you and Jack respond promptly to his questions to expedite the process.

Normally, it is optimal to do a patentability search in advance of the application to minimize the risk of denial. You have asked that the search be deferred until later so that you can meet your Sept. 23rd deadline and to avoid the extra cost. After the meeting, you might want to do a search so that you can amend the application (to the extent possible) to better avoid the prior art, and so maximize the odds of patentability. If you could afford to, it would be best to pay for the patentability search now so that it could be done while your application is being developed, and the results incorporated into the application before filing. However, because of cost considerations, I will assume you are willing to bear the risk of omitting or deferring a patentability search.

Please call if you have any questions. I will be at (509) 663-2225 from Friday until Tuesday.

Very truly yours,

OLES, MORRISON & RINKER

Richard T. Black

Richard T. Black

cc: Douglas S. Oles

Exhibit 7

OLES, MORRISON & RINKER
LAWYERS

SETH W MORRISON
BRUCE T. RINKER
DAVID C. STEWART
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ARTHUR D. MCGARRY
B. MICHAEL SCHESTOPOL
THEODORE L. PREG
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J. CRAIG RUSK
JOHN F. JENKEL

STUART G. OLES
OF COUNSEL

GERALD DE GARMO
(1903-1988)

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JON G. HONGLADAROM
TRAEGER MACHETANZ
TODD M. NELSON
BRIAN E. ONORATO
ROBERT W. SARGEANT

September 15, 1992

James W. Anable, Esq.
Christensen, O'Connor, Johnson & Kindness
2800 Pacific First Center
1420 Fifth Avenue
Seattle, WA 98101

RE: Raya Systems, Inc.

Dear Jim:

Enclosed is Raya's check in the amount of $6,000 as a retainer for your work on Raya's patent. Please forward a receipt to Raya.

Very truly yours,

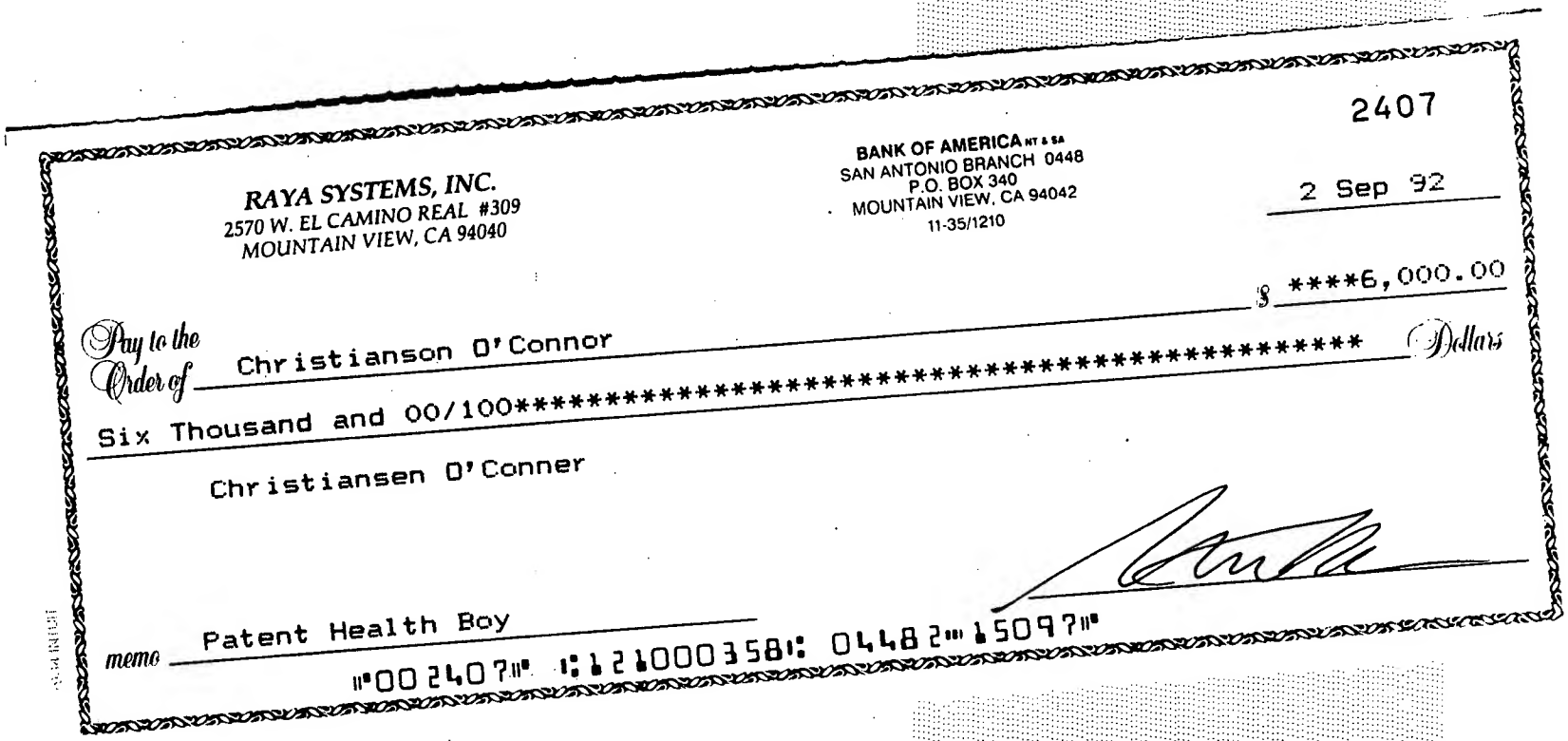
OLES, MORRISON & RINKER

Richard T. Black

Richard T. Black

RTB/jd
Enclosure
cc: Douglas Oles, Esq.

6228-001
RTB20915.001



2407

RAYA SYSTEMS, INC.
2570 W. EL CAMINO REAL #309
MOUNTAIN VIEW, CA 94040

BANK OF AMERICA NT & SA
SAN ANTONIO BRANCH 0448
P.O. BOX 340
MOUNTAIN VIEW, CA 94042
11-35/1210

2 Sep 92

Pay to the Order of Christianson O'Connor $ ****6,000.00

Six Thousand and 00/100********** Dollars

Christiansen O'Conner

memo Patent Health Boy

⑈002407⑈ ⑆121000358⑆ 04482⑈15097⑈

Exhibit 8

O'CONNOR JOHNSON KINDNESS

PATENT, TRADEMARK AND OTHER INTELLECTUAL PROPERTY MATTERS

FAX: (206) 224-0779
TELEX: 4938023
CABLE: PATENTABLE

FACSIMILE COVER SHEET

DATE: October 2, 1992

TO: Steve Brown/Jack Thornton

Raya Systems, Inc.

FACSIMILE NUMBER: (415) 949-3935

RE: Patent Application

OUR REFERENCE: RAYA-1-6631

YOUR REFERENCE:

FROM: James W. Anable, Esq.

(Facsimile No. (206) 224-0779 - Panafax Groups 1, 2 & 3)

MESSAGE:

Please review and contact me. I am out of the office this morning but expect to return by noon. I will await your call.

Enclosures: Patent Application (DRAFT) and drawings (DRAFT)

*** The information contained in this facsimile message is privileged and confidential information intended only for the use of the recipient named above. If the reader of this message is not the intended recipient, or the employee or agent responsible to deliver it to the intended recipient, any distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone and return the original message to us at the above address by mail. ***

We have 34 pages to send, including this sheet. If any pages need to be retransmitted, please call (206) 682-8100, Ext. ____, within 15 minutes.

This document was transmitted at _____:_____ ___m.

MODULAR MICROPROCESSOR-BASED HEALTH MONITORING SYSTEM

Field of the Invention

This invention relates to administering and monitoring personal healthcare. More specifically, this invention relates to self-care health monitoring arrangements that enable a patient or other user to gather data important to a health management program and, if desired or necessary, easily provide that data to a healthcare professional.

Background of the Invention

Controlling or curing conditions of ill health generally involves both establishing a therapeutic program and monitoring the progress of the afflicted person. Based on that progress, decisions can be made as to altering therapy to achieve a cure or maintain the affliction or condition at a controlled level. Successfully treating certain health conditions calls for rather frequent monitoring and a relatively high degree of patient participation. For example, in order to establish and maintain a regimen for successful diabetes care, a diabetic should monitor his or her blood glucose level and record that information along with the date and time at which the monitoring took place. Since diet, exercise, and medication all affect blood glucose levels, a diabetic often must record data relating to those items of information along with blood glucose level so that the diabetic may more closely monitor his or her condition and, in addition, can provide information of value to

the healthcare provider in determining both progress of the patient and detecting any need to change the patient's therapy program.

Advances in the field of electronics over the past several years have brought about significant changes in medical diagnostic and monitoring equipment, including arrangements for self-care. With respect to the control and monitoring of diabetes, relatively inexpensive and relatively easy-to-use blood glucose monitoring systems have become available that provide reliable information that allows a diabetic and his or her healthcare professional to establish, monitor and adjust a treatment plan (diet, exercise, and medication). More specifically, microprocessor-based blood glucose monitoring systems are being marketed which sense the glucose level of a blood sample that is applied to a reagent-impregnated region of a test strip that is inserted in the glucose monitor. When the monitoring sequence is complete, the blood glucose level is displayed by, for example, a liquid crystal display (LCD) unit.

Typically, currently available self-care blood glucose monitoring units include a calendar/clock circuit and a memory circuit that allows a number of blood glucose test results to be stored along with the date and time at which the monitoring occurred. The stored test results (blood glucose level and associated time and date) can be sequentially recalled for review by the blood glucose monitor user or a health professional by sequentially actuating a push button or other control provided on the monitor. In some commercially available devices, the average of the blood glucose results that are stored in the monitor (or the average of the results for a predetermined period of time, e.g., fourteen days) also is displayed during the recall sequence. Further, some self-care blood glucose monitors allow the user to tag the test result with an "event code" that can be used to organize the test results into categories. For example, a user might use a specific event code to identify test results obtained at a particular times of the day, a different

event code to identify a blood glucose reading obtained after a period of exercise, two additional event codes to identify blood glucose readings taken during hypoglycemia symptoms and hyperglycemia symptoms, etc. When event codes are provided and used, the event code typically is displayed with each recalled blood glucose test result.

Microprocessor-based blood glucose monitoring systems have advantages other than the capability of obtaining reliable blood glucose test results and storing a number of the results for later recall and review. By using low power microprocessor and memory circuits and powering the units with small, high capacity batteries (e.g., a single alkaline battery), extremely compact and light designs have been achieved that allow taking the blood glucose monitoring system to work, school, or anywhere else the user might go with people encountered by the user not becoming aware of the monitoring system. In addition, most microprocessor-based self-care blood glucose monitoring systems have a memory capacity that allows the system to be programmed by the manufacturer so that the monitor displays a sequence of instructions during any necessary calibration or system tests and during the blood glucose test sequence itself. In addition, the system monitors various system conditions during a blood glucose test (e.g., whether a test strip is properly inserted in the monitor and whether a sufficient amount of blood has been applied to the reagent impregnated portion of the strip) and if an error is detected generates an appropriate display (e.g., "retest"). A data port may be provided that allows test results stored in the memory of the microprocessor-based blood glucose monitoring system to be transferred to a data port (e.g., RS-232 connection) of a personal computer or other such device for subsequent analysis.

Microprocessor-based blood glucose monitoring systems are a significant advance over previously available self-care systems such as those requiring a diabetic to apply a blood sample to reagent activated portions of a test strip; wipe the blood sample from the

test strip after a predetermined period of time; and, after a second predetermined period of time, determine blood glucose level by comparing the color of the reagent activated regions of the test strip with a color chart supplied by the test strip manufacturer. However, several drawbacks and disadvantages exist, thus leaving several areas in which improvements would be of benefit both to the user and the healthcare professional. For example, establishing and maintaining diabetic healthcare often requires the diabetic to record additional data pertaining to medication, food intake, and exercise. However, the event codes of currently available microprocessor blood glucose monitoring systems do not allow the user of the system to tag and track blood glucose test results on a sufficiently accurate quantitative basis. For example, it would only be possible for the user to use the available event codes to classify stored blood glucose readings to indicate blood glucose tests taken immediately after a heavy meal and to identify blood glucose test results obtained after normal and light meals. This method of recording information not only requires subjective judgment by the system user, but will not suffice in a situation in which successfully controlling the user's diabetes requires the recording and tracking of relatively accurate information relating to food intake, exercise, or medication (e.g., insulin dosage). An otherwise significant advantage of currently available blood glucose monitoring systems is lost when blood glucose test results must be recorded and tracked with quantitative information relating to medication, food intake, or exercise. Specifically, the system user must record the required information along with a time and date tagged blood glucose test result by, for example, writing the information in a log book.

The use of event codes to establish subcategories of blood glucose test results has an additional disadvantage or drawback. In particular, although alphanumeric display devices are typically used in currently available microprocessor-based blood glucose

monitoring systems, the display units are limited to a single line of information having on the order of six characters. Moreover, since the systems include no provision for the user to enter alphanumeric information, any event codes that are used must be indicated on the display in a generic manner, e.g., displayed as "EVENT 1", "EVENT 2", etc. This limitation makes the system more difficult to use because the diabetic must either memorize his or her assignment of event codes or maintain a list that defines the event codes. The limited amount of data that can be displayed at any one time presents additional drawbacks and disadvantages. First, instructions and diagnostics that are displayed to the user when calibrating the system and using the system to obtain a blood glucose reading must be displayed a line at a time and in many cases, the information must be displayed in a cryptic manner. This limitation increases the likelihood that some potential users of the system (particularly children and the elderly) either will find the system complex to use or will not achieve the maximum benefit available from system use.

The above-discussed display limitations and other aspects of currently available blood glucose monitoring systems is disadvantageous in yet another way. Little statistical information can be made available to the user. For example, in diabetic healthcare maintenance, changes or fluctuations that occur in blood glucose levels during a day, a week, or longer period can provide valuable information to a diabetic and/or his or her healthcare professional. As previously mentioned, currently available systems do not allow associating blood glucose test results with attendant quantitative information relating to medication, food intake, or other factors such as exercise that affect a person's blood glucose level at any particular point in time. Thus, currently available blood glucose monitoring systems are not able to generate or display trend information that may be of significant value to a diabetic or the diabetic's healthcare professional.

The lack of provision for the entering of alphanumeric data also can be a disadvantage. For example, currently available blood glucose monitoring systems do not allow the user or the healthcare professional to enter information into the system such as medication dosage and other instructions or data that is relevant to the user's self-care health program.

The above-discussed disadvantages and drawbacks of currently available microprocessor-based blood glucose monitoring systems also have been impediments to adopting the basic technology of the system for other healthcare situations in which establishing and maintaining an effective regimen for cure or control is dependent upon (or at least facilitated by) periodically monitoring a condition and recording that condition along with time and date tags and other information necessary or helpful in establishing and maintaining a healthcare program.

Summary of the Invention

This invention provides a new and useful system for healthcare maintenance in which the invention serves as a peripheral device to a small handheld microprocessor-based unit of the type that includes a display screen, buttons or keys that allow a user to control the operation of the device and a program cartridge or other arrangement that can be inserted in the device to adapt the device to a particular application or function. The invention in effect converts the handheld microprocessor device into a healthcare monitoring system that has significant advantages over systems such as the currently available blood glucose monitoring systems. To perform this conversion, the invention includes a microprocessor-based healthcare data management unit, a program cartridge and a monitoring unit. When inserted in the handheld microprocessor unit, the program cartridge provides the software necessary to program the handheld microprocessor unit for operation with the microprocessor-based data management unit. Signal

communication between the data management unit and the handheld microprocessor unit is established by an interface cable. A second interface cable can be used to establish signal communication between the data management unit and the monitoring unit or, alternatively, the monitoring unit can be constructed as a plug-in unit having an electrical connector that mates with a connector mounted within a region that is configured for receiving the monitoring unit.

In operation, the control buttons or keys of the handheld microprocessor-based unit are used to select the operating mode for both the data management unit and the handheld microprocessor-based unit. In response to signals generated by the control buttons or keys, the data management unit generates signals that are coupled to the handheld microprocessor unit and, under control of the software contained in the program cartridge, establish an appropriate screen display on the handheld microprocessor-based unit display. In selecting system operating mode and other operations, the control buttons are used to position a cursor or other indicator in a manner that allows the system user to easily select a desired operating mode or function and provide any other required operator input. In the disclosed detailed embodiment of the invention several modes of operation are made available.

Brief Description of the Drawings

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same becomes better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIGURE 1 is a block diagram that illustrates a healthcare monitoring system arranged in accordance with the invention;

FIGURE 2 diagrammatically illustrates monitoring systems constructed in accordance with the invention connected in signal communication with a remotely located computing facility which includes provision for making the data supplied by the monitoring system of the invention available to a designated healthcare professional and/or for providing data and instructions to the system user;

FIGURE 3 is a block diagram diagrammatically depicting the structural arrangement of the system data management unit and its interconnection with other components of the system shown in FIGURE 1; and

FIGURES 4-10 depict typical system screen displays of data and information that can be provided by the arrangements shown in FIGURES 1-3.

Detailed Description

FIGURE 1 depicts a self-care health monitoring system arranged in accordance with the invention. In the arrangement shown in FIGURE 1, a data management unit 10 is electrically interconnected with a handheld microprocessor-based unit 12 via a cable 14. Data management unit 10 also is electrically interconnected with a blood glucose monitor 16 of the type capable of sensing blood glucose level and producing an electrical signal representative thereof. Although FIGURE 1 illustrates blood glucose monitor 16 as being connected to data management unit 10 by a cable 18, it may be preferable to construct blood glucose monitor 16 as a plug-in unit that is placed in a recess or other suitable opening or slot in data management unit 10. Regardless of the manner in which blood glucose monitor 16 is interconnected with data management unit 10, both that interconnection and cable 14 are configured for serial data communication between the interconnected devices.

Also shown in FIGURE 1 are two additional monitoring devices 20 and 22, which are electrically connected for serial data communication with data management unit 10

via cables 24 and 26, respectively. Monitoring units 20 and 22 of FIGURE 1 represent devices other than blood glucose monitor 16 that can be used in the practice of the invention. For example, monitors can be provided for monitoring conditions such as blood pressure, pulse, and body temperature to thereby realize systems for self-care monitoring and control of conditions such as hypertension, certain heart conditions and various other afflictions and physical conditions. As is the case with blood glucose monitor 16, the additional monitors can be configured as plug-in units that are directly received by data management unit 10, or can be connected to data management unit 10 with cables (as shown in FIGURE 1).

As is shown in FIGURE 1, handheld microprocessor unit 12 includes a display screen 28 and a plurality of switches or keys (30, 32, 34, 36, and 38 in FIGURE 1), which are mounted on a small housing 40. Located in the interior of housing 40, but not shown in FIGURE 1, are a microprocessor, memory circuits, and circuitry that interfaces switches 30, 32, 34, 36 and 38 with the microprocessor. Stored in the memory of program handheld microprocessor unit 12 is a set of program instructions that establishes a data protocol that allows handheld microprocessor unit 12 to perform digital data signal processing and generate desired data or graphics for display on display unit 28 when a program cartridge 42 is inserted in a slot or other receptacle in housing 40. That is, program cartridge 42 includes read-only memory units (or other memory means such as battery-powered random access memory) which stores program instructions and data. When combined with program instructions and data included in the internal memory circuits of handheld microprocessor unit 12, the instructions and data of program cartridge 42 cause handheld microprocessor unit 12 to be programmed for a particular purpose or use. As is known in the art, the program instructions and data stored in the internal memory of handheld microprocessor-based unit 12 can be configured and

arranged so that different program cartridges configure handheld microprocessor unit 12 for different applications or purposes. In each such purpose or application, the plurality of switches or keys (30, 32, 34, 36, and 38 in FIGURE 1) are selectively operated to provide signals that result in pictorial and/or printed information being displayed by display unit 42.

Various devices are known that meet the above-set forth description of handheld microprocessor unit 12. For example, compact devices are available in which the plurality of keys allows alphanumeric entry and internal memory is provided for storing information such as names, addresses, phone numbers, and an appointment calendar. Small program cartridges or cards can be inserted in these devices to program the device for various purposes such as the playing of games, spreadsheet application, and foreign language translation sufficient for use in travel. More recently, less compact products that have more extensive computational capability and are generally called "palm top computers" have been introduced into the marketplace. These devices also can include provision for programming the device by means of an insertable program card or cartridge.

The currently preferred embodiments of the invention are configured and arranged to operate in conjunction with yet another type of handheld microprocessor unit. Specifically, in the currently preferred embodiments of the invention, program cartridge 42 is electrically and physically compatible with commercially available compact video game systems, such as the system manufactured by Nintendo of America Inc. under the trademark "GAME BOY." Configuring data management unit 10 and program cartridge 42 for operation with a handheld video game system has several advantages. For example, the display unit of such a device provides display resolution that allows the invention to display both multi-line alphanumeric information and graphical data. In this

regard, the 160 x 144 pixel dot matrix-type liquid crystal display screen currently used in the above-referenced compact video game systems provides sufficient resolution for at least six lines of alphanumeric text, as well as allowing graphical representation of statistical data such as graphical representation of blood glucose test results for a day, a week, or longer.

Another advantage of realizing handheld microprocessor unit 12 in the form of a compact video game system is the relatively simple, yet versatile arrangement of switches that is provided by such a device. For example, as is indicated in FIGURE 1, a compact video game system includes a control pad 30 that allows an object displayed on display unit 42 to be moved in a selected direction (i.e., up-down or left-right). As also is indicated in FIGURE 1, compact video game systems typically provide two pair of distinctly-shaped push button switches. In the arrangement shown in FIGURE 1, a pair of spaced-apart circular push button switches (36 and 38) and a pair of elongate switches (32 and 34) are provided. The functions performed by the two pairs of switches is dependent upon the program instructions contained in each program cartridge 42.

Yet another advantage of utilizing a compact video game system for handheld microprocessor based unit 12 of FIGURE 1 is the widespread popularity and low cost of such units. In this regard, manufacture and sale of a data management unit 10, blood glucose monitor 16 and program cartridge 42 that operate in conjunction with a compact microprocessor based video allows the self-care health monitoring system of FIGURE 1 to be manufactured and sold at a lower cost than could be realized in an arrangement in which handheld unit 12 is designed and manufactured solely for use in the system of FIGURE 1.

An even further advantage of using a compact video game system for handheld microprocessor 12 is that such video game systems include means for easily establishing

the electrical interconnection provided by cable 14 in FIGURE 1. In particular, such compact video game systems include a connector mounted to the game unit housing (40 in FIGURE 1) and a cable that can be connected between the connectors of two video game units to allow interactive operation of the two interconnected units (i.e., to allow contemporaneous game play by two players or competition between players as they individually play identical but separate games). In the preferred embodiments of the invention, the "two-player" cable supplied with the compact video game unit being used as handheld microprocessor unit 12 is used as cable 14 to establish serial data communication between the handheld microprocessor unit 12 (compact video game system) and data management unit 10. In these preferred embodiments, the program instructions stored on the memory of data management unit 10 and program cartridge 42 respectively program data management unit 10 and the compact video game system (i.e., handheld microprocessor unit 12) for interactive operation in which switches 30, 32, 34, 36 and 38 are used to control the operation of data management unit 10 (e.g., to select a particular operational mode such as performance of a blood glucose test or the display of statistical test data and, in addition, to control operation such as selection of an option during operation of the system in a particular operational mode). In each operational mode, data management unit 10 processes data in accordance with program instructions stored in the memory circuits of data management unit 10. Depending upon the operational mode selected by the user, data is supplied to data management unit 10 by blood glucose monitor 16, by additional monitors (20 and 22 in FIGURE 1) or any interconnected computers (hereinafter described as elements 48 and 54 in FIGURE 1) During operational mode, switches 30, 32, 34, 36 and 38 are selectively activated so that signals are selectively coupled to the video game system (handheld microprocessor unit 12) and processed in accordance with program instructions stored in program

cartridge 42. The signal processing performed by handheld microprocessor unit 12 results in the display of alphanumeric, symbolic, or graphic information on the video game display screen (i.e., display unit 28 in FIGURE 1) which allow the user to control system operation and obtain desired test results and other information.

With continued reference to FIGURE 1, data management unit 10 of the currently preferred embodiments of the invention includes a data port 44 that allows communication between data management unit 10 and a personal computer 48 (or other programmable data processor). In the currently preferred embodiments of the invention, data port 44 is an RS-232 connection that allows serial data communication between data management unit 10 and personal computer 48. In the practice of the invention, personal computer 48 can be used to supplement data management unit 10 by, for example, performing relatively complex or sophisticated analyses of blood glucose and other data that has been supplied to and stored in the memory circuits of data management unit 10. Alternatively, personal computer 48 can be used to supply data to data management unit 10 that is not conveniently supplied by using handheld microprocessor switches 30, 32, 34, 36 and 38 as an operator interface to the system shown in FIGURE 1. For example, some embodiments of the invention may employ a substantial amount of alphanumeric information that must be entered by the system user. Although it is possible to enter such data by using switches 30, 32, 34, 36 and 38 in conjunction with menus and selection screens displayed on display screen 28 of FIGURE 1, it may be more advantageous to use a device such as personal computer 48 for entry of such data. However, if personal computer 48 is used in this manner, some trade-off of system features may be required because data management unit 10 must be temporarily interconnected with personal computer 48 during these operations. That is, some loss of

system mobility might result because a suitably programmed personal computer would be needed at each location at which data entry or analysis is to occur.

As is indicated in FIGURE 1, data management unit 10 of the currently preferred embodiments of the invention also includes a modem that allows data communication between data management unit 10 and a remote computing facility 54 via a conventional telephone line (indicated by reference numeral 50 in FIGURE 1) and a modem 52 that interconnects remote computing facility 54 and telephone line 50. As shall be described in more detail, remote computing facility 54 facilitates communication between a user of the system shown in FIGURE 1 and his or her healthcare professional and can provide additional services such as updating system software.

Regardless of whether a compact video game system, another type of commercially available handheld microprocessor-based unit, or a specially designed unit is used, the preferred embodiments of FIGURE 1 provide a self-care blood glucose monitoring system in which program cartridge 42: (a) adapts handheld microprocessor unit 12 for displaying instructions for performing the blood glucose test sequence and associated calibration and test procedures; (b) adapts handheld microprocessor unit 12 for displaying (graphically or alphanumerically) statistical data such as blood glucose test results taken during a specific period of time (e.g., a day, week, etc.); (c) adapts handheld microprocessor unit 12 for supplying control signals and signals representative of food intake or other useful information to data management unit 10; (d) adapts handheld microprocessor unit 12 for simultaneous graphical display of blood glucose levels with information such as food intake; and, (e) adapts handheld microprocessor unit 12 for displaying information or instructions from a healthcare professional that are coupled to data management unit 10 from a remote computing facility 54. The manner in which the

arrangement of FIGURE 1 implements the above-mentioned functions and others can be better understood with reference to FIGURES 2 and 3.

Referring first to FIGURE 2, in relatively large scale application of the invention, remote computing facility 54 of FIGURE 1 functions as a clearinghouse (i.e., central server) that is identified by reference numeral 56 in FIGURE 2. Clearinghouse 56 receives data from a plurality of self-care microprocessor-based healthcare systems of the type shown in FIGURE 1, with the individual self-care health monitoring systems being indicated in FIGURE 2 by reference numeral 58. Preferably, the data supplied to clearinghouse 56 by each individual self-care health monitoring system 58 consists of "raw data," i.e., test results and related data that was stored in memory circuits of data management unit 10, without further processing by data management unit 10. For example, with respect to the arrangement shown in FIGURE 1, blood glucose test results and associated data such as food intake information, medication dosage and other such conditions are transmitted to clearinghouse 56 and stored with a digitally encoded signal that identifies both the source of the information (i.e., the system user or patient) and those having access to the stored information (i.e., the system user's doctor or other healthcare professional).

In FIGURE 2, rectangular outline 60 represents one of numerous remotely located healthcare professionals who can utilize clearinghouse 56 and the arrangement described relative to FIGURE 1 in monitoring and controlling patient healthcare programs. Shown within outline 60 is a computer 62 (e.g., personal computer), which is coupled to clearinghouse 56 by means of a modem (not shown in FIGURE 2) and a telephone line 64. The arrangement of FIGURE 2 also diagrammatically indicates a facsimile machine ("fax"), which is coupled to clearinghouse 56 by means of a second

device such as a mouse), the healthcare professional can establish data communication between computer 62 and clearinghouse 56 via telephone line 64. Once data communication is established between computer 62 and clearinghouse 56, patient information can be obtained from clearinghouse 56 in a manner similar to the manner in which subscribers to various database services access and obtain information. In particular, the healthcare professional can transmit an authorization code to clearinghouse 56 that identifies the healthcare professional as an authorized user of the clearinghouse and, in addition, can transmit a signal representing the patient for which healthcare information is being sought. As is the case with conventional database services and other arrangements, the identifying data is keyed into computer 62 by means of a conventional keyboard (not shown in FIGURE 2) in response to prompts that are generated at clearinghouse 56 for display by the display unit of computer 62 (not shown in FIGURE 2).

Depending upon the hardware and software arrangement of clearinghouse 56 and selections made by the healthcare professional via computer 62, patient information can be provided to the healthcare professional in different ways. For example, computer 62 can be operated to access data in the form that it is stored in the memory circuits of clearinghouse 56 (i.e., raw data that has not been processed or altered by the computational or data processing arrangements of clearinghouse 56). Such data can be processed, analyzed, printed and/or displayed by computer 62 using commercially available or custom software. On the other hand, various types of analyses may be performed by clearinghouse 56 with the results of the analyses being transmitted to the remotely located healthcare professional 60. For example, clearinghouse 56 can process and analyze data in a manner identical to the processing and analysis provided by the self-care monitoring system of FIGURE 1. With respect to such processing and any other

analysis and processing provided by clearinghouse 56, results expressed in alphanumeric format can be sent to computer 62 via telephone line 64 and the modem associated with computer 62, with conventional techniques being used for displaying and/or printing the alphanumeric material for subsequent reference. In addition, the arrangement of FIGURE 2 allows analytical or statistical results to be transmitted to remotely located healthcare professional 60 via telephone line 68 and facsimile machine 66. For example, data supplied by the arrangement can be processed by clearinghouse 56 using conventional data processing techniques to obtain a collection of data or statistical information that lends itself to presentation in a pictorial or graphic format. In such a case, the data can be converted by clearinghouse 56 to a conventional facsimile transmission format, which can be sent to the healthcare professional's facsimile machine 66 upon request of the healthcare professional (i.e., communication via computer 62).

The arrangement of FIGURE 2 also allows the healthcare professional to send messages and/or instructions to each patient via computer 62, telephone line 64, and clearinghouse 56. In particular, clearinghouse 56 can be programmed to generate a menu that is displayed by computer 62 and allows the healthcare professional to select a mode of operation in which information is to be sent to clearinghouse 56 for subsequent transmission to a user of the system described relative to FIGURE 1. This same menu (or related submenus) can be used by the healthcare professional to select one or more modes of operation of the above-described type in which either unmodified patient data or the results of data that has been analyzed by clearinghouse 56 is provided to the healthcare provider via computer 62 and/or facsimile machine 66.

In the currently contemplated arrangements, operation of the arrangement of FIGURE 2 to provide the user of the invention with messages or instructions such as

changes in medication or other aspects of the healthcare program is similar to the operation that allows the healthcare professional to access data sent by a patient, i.e., transmitted to clearinghouse 56 by a data management unit 10 of FIGURE 1. The process differs in that the healthcare professional enters the desired message or instruction via the keyboard or other interface unit of computer 62. Once the data is entered and transmitted to clearinghouse 56, it is stored for subsequent transmission to the user for whom the information or instruction is intended.

With respect to transmitting stored messages or instructions to a user of the invention, at least two techniques are available. The first technique is based upon the manner in which operational modes are selected in the practice of the invention. Specifically, in the currently preferred embodiments of the invention, program instructions that are stored in data management unit 10 and program cartridge 42 cause the system of FIGURE 1 to generate menu screens which are displayed by display unit 28 of handheld microprocessor unit 12. The menu screens allow the system user to select the basic mode in which the system of FIGURE 1 is to operate and, in addition, allow the user to select operational subcategories within the selected mode of operation. Various techniques are known to those skilled in the art for displaying and selecting menu items. For example, in the practice of this invention, one or more main menus can be generated and displayed which allow the system user to select operational modes that may include: (a) a monitor mode (e.g., monitoring of blood glucose level); (b) a display mode (e.g., displaying previously obtained blood glucose test results or other relevant information); (c) an input mode (e.g., a mode for entering data such as providing information that relates to the healthcare regimen, medication dosage, food intake, etc., and (d) a communications mode (for establishing a communication link between data management

unit 10 and personal computer 48 of FIGURE 1; or between data management Unit 10 and a remote computing facility such as clearinghouse 56 of FIGURE 2).

In embodiments of the invention that employ a compact video game system for handheld microprocessor unit 12, the selection of menu screens and the selection of menu screen items preferably is accomplished in substantially the same manner as menu screens and menu items are selected during the playing of a video game. For example, the program instructions stored in data management unit 10 and program cartridge 42 of the arrangement of FIGURE 1 can be established so that a predetermined one of the compact video game switches (e.g., switch 32 in FIGURE 1) allows the system user to select a desired main menu in the event that multiple main menus are employed. When the desired main menu is displayed, operation by the user of control pad 30 allows a cursor or other indicator that is displayed on the menu to be positioned adjacent to or over the menu item to be selected. Activation of a switch (e.g., switch 36 of the depicted handheld microprocessor unit 12) causes the handheld microprocessor unit 12 and/or data management unit 10 to initiate the selected operational mode or, if selection of operational submodes is required, causes handheld microprocessor unit 12 to display a submenu.

In view of the above-described manner in which menus and submenus are selected and displayed, it can be recognized that the arrangement of FIGURE 1 can be configured and arranged to display a menu or submenu item that allows the user to obtain and display messages or instructions that have been provided by a healthcare professional and stored in clearinghouse 56. For example, a submenu that is generated upon selection of the previously mentioned communications mode can include submenu items that allow the user to select various communication modes, including a mode in which serial data communication is established between data management unit 10 and clearinghouse 56 and

data management unit 10 transmits a message status request to clearinghouse 56. When this technique is used, the data processing system of clearinghouse 56 is programmed to search the clearinghouse memory to determine whether a message exists for the user making the request. Any messages stored in memory for that user are then transmitted to the user and processed for display on display unit 28 of handheld microprocessor unit 12. If no messages exist, clearinghouse 56 transmits a signal that causes display unit 28 to indicate "no messages." In this arrangement, clearinghouse 56 preferably is programmed to store a signal indicating that a stored message has been transmitted to the intended recipient (user). Storing such a signal allows the healthcare professional to determine that messages sent to clearinghouse 56 for forwarding to a patient have been transmitted to that patient. In addition, the program instructions stored in data management unit 10 of FIGURE 1 preferably allow the system user to designate whether received messages and instructions are to be stored in the memory of data management unit 10 for subsequent retrieval or review. In addition, in some instances it may be desirable to program clearinghouse 56 and data management unit 10 so that the healthcare professional can designate (i.e., flag) information such as changes in medication that will be prominently displayed to the user (e.g., accompanied by a blinking indicator) and stored in the memory of data management unit 10 regardless of whether the system user designates the information for storage.

A second technique that can be used for forwarding messages or instructions to a user does not require the system user to select a menu item requesting transmission by clearinghouse 56 of messages that have been stored for forwarding to that user. In particular, clearinghouse 56 can be programmed to operate in a manner that either automatically transmits stored messages for that user when the user operates the system of FIGURE 1 to send information to the clearinghouse or programmed to operate in a

manner that informs the user that messages are available and allows the user to access the messages when he or she chooses to do so.

FIGURE 3 illustrates the manner in which data management unit 10 is arranged and interconnected with other system components for effecting the above-described operational aspects of the invention and additional aspects that are described relative to FIGURES 4-10. As is symbolically indicated in FIGURE 3, handheld microprocessor unit 12 and blood glucose monitor 16 are connected to a dual universal asynchronous receiver transmitter 70 (e.g., by cables 14 and 18 of FIGURE 1, respectively). As also is indicated in FIGURE 3 when a personal computer 48 (or other programmable digital signal processor) is connected to data port 44 signal communication is established between personal computer 48 and a second dual universal asynchronous receiver transmitter 72, which is included in data management unit 10. Additionally, dual universal asynchronous receiver transmitter 72 is coupled to modem 46 so that data communication can be established between data management unit 10 and a remote computing facility 54 (e.g., clearinghouse 56 of FIGURE 2).

Currently preferred embodiments of data management unit 10 include a plurality of signal sensors 74, with an individual signal sensor being associated with each device that is (or may be) interconnected with data management unit 10. As previously discussed and as is indicated in FIGURE 3, these devices include handheld microprocessor unit 12, blood glucose monitor 16, personal computer 48, and remote computing facility 54. Each signal sensor 74 that is included in data management unit 10 is electrically connected for receiving a signal that will be present when the device with which that particular signal sensor is associated is connected to data management unit 10 and, in addition, is energized (e.g., turned on). For example, in previously mentioned embodiments of the invention in which data port 44 is an RS-232 connection, the signal

sensor 74 that is associated with personal computer 48 can be connected to an RS-232 terminal that is supplied power when a personal computer is connected to data port 44 and the personal computer is turned on. In a similar manner, the signal sensor 74 that is associated with remote computing facility 54 can be connected to modem 46 so that the signal sensor 74 receives an electrical signal when modem 46 is interconnected to a remote computing facility (e.g., clearinghouse 56 of FIGURE 2) via a telephone line 50.

In the arrangement of FIGURE 3, each signal sensor 74 is a low power switch circuit (e.g., a metal-oxide semiconductor field-effect transistor circuit), which automatically energizes data management unit 10 whenever one or more of the devices associated with signal sensors 74 are connected to data management unit 10 and are energized. Thus, as is indicated in FIGURE 3 by signal path 76, each signal sensor 74 is interconnected with power supply 78, which supplies operating current to the circuitry of data management unit 10 and typically consists of one or more small batteries (e.g., three AAA alkaline cells).

The microprocessor and other conventional circuitry that enables data management unit 10 to process system signals in accordance with stored program instructions is indicated in FIGURE 3 by central processing unit (CPU) 80. As is indicated in FIGURE 3 by interconnection 82 between CPU 80 and battery 78, CPU 80 receives operating current from power supply 78, with power being provided only when one or more of the signal sensors 74 are activated in the previously described manner. A clock/calendar circuit 84 is connected to CPU 80 (via signal path 86 in FIGURE 3) to allow time and date tagging of blood glucose tests and other information. Although not specifically shown in FIGURE 3, operating power is supplied to clock/calendar 84 at all times.

In operation, CPU 80 receives and sends signals via a data bus (indicated by signal path 88 in FIGURE 3) which interconnects CPU 80 with dual universal asynchronous receiver transmitters 70 and 72. The data bus 88 also interconnects CPU 80 with memory circuits which, in the depicted embodiment, include a system read-only memory (ROM) 90, a program random access memory (RAM) 92, and an electronically erasable read-only memory (EEROM) 94. System ROM 90 stores program instructions and any data required in order to program data management unit 10 so that data management unit 10 and a handheld microprocessor unit 12 that is programmed with a suitable program cartridge 72 provide the previously discussed system operation and system operation that will be described relative to FIGURES 4-10. During operation of the system, program RAM 92 provides memory space that allows CPU 80 to carry out various operations that are required for sequencing and controlling the operation of the system of FIGURE 1. In addition, RAM 92 can provide memory space that allows external programs (e.g., programs provided by clearinghouse 56) to be stored and executed. EEROM 94 allows blood glucose test results and other data information to be stored and preserved until the information is no longer needed (i.e., until purposely erased by operating the system to provide an appropriate erase signal to EEROM 94).

FIGURES 4-10 illustrate typical screen displays that are generated by the arrangement of the invention described relative to FIGURES 1-3. Reference will first be made to FIGURES 4 and 5, which exemplify screen displays that are associated with operation of the invention in the blood glucose monitoring mode. Specifically, in the currently preferred embodiments of the invention, blood glucose monitor 16 operates in conjunction with data management unit 10 and handheld microprocessor unit 12 to: (a) perform a test or calibration sequence in which tests are performed to confirm that the system is operating properly; and, (b) perform the blood glucose test sequence in which

blood glucose meter 16 senses the user's blood glucose level. Suitable calibration procedures for blood glucose monitors are known in the art. For example, blood glucose monitors often are supplied with a "code strip," that is inserted in the monitor and results in a predetermined value being displayed and stored in memory at the conclusion of the code strip calibration procedure. When such a code strip calibration procedure is used in the practice of the invention, the procedure is selected from one of the system menus. For example, if the system main menu includes a "monitor" menu item, a submenu displaying system calibration options and an option for initiating the blood glucose test may be displayed when the monitor menu item is selected. When a code strip option is available and selected, a sequence of instructions is generated and displayed by display screen 28 of handheld microprocessor unit 12 to prompt the user to insert the code strip and perform all other required operations. At the conclusion of the code strip calibration sequence, display unit 28 of handheld microprocessor unit 12 displays a message indicating whether or not the calibration procedure has been successfully completed. For example, FIGURE 4 illustrates a screen display that informs the system user that the calibration procedure was not successful and that the code strip should be inserted again (i.e., the calibration procedure is to be repeated). As is indicated in FIGURE 4, display screens that indicate a potential malfunction of the system include a prominent message such as the "Attention" notation included in the screen display of FIGURE 4.

As previously indicated, the blood glucose test sequence that is employed in the currently preferred embodiment of the invention is of the type in which a test strip is inserted in a receptacle that is formed in the blood glucose monitor. A drop of the user's blood is then applied to the test strip and a blood glucose sensing sequence is initiated. When the blood glucose sensing sequence is complete, the user's blood glucose level is displayed.

In the practice of the invention, program instructions stored in data management unit 10 (e.g., system ROM 90 of FIGURE 3) and program instructions stored in program cartridge 42 of handheld microprocessor unit 12 cause the system to display step-by-step monitoring instructions to the system user and, in addition, preferably result in display of diagnostic messages if the test sequence does not proceed in a normal fashion. Although currently available self-contained microprocessor base blood glucose monitors also display test instruction and diagnostic messages, the invention provides greater message capacity and allows multi-line instructions and diagnostic messages that are displayed in easily understood language rather than cryptic error codes and abbreviated phraseology that is displayed one line at a time. For example, as is shown in FIGURE 5, the complete results of a blood glucose test (date, time of day, and blood glucose level in milligrams per deciliter) can be concurrently displayed by display screen 28 of handheld microprocessor unit 12 along with an instruction to remove the test strip from blood glucose monitor 16. As previously mentioned, when the blood glucose test is complete, the time and date tagged blood glucose test result is stored in the memory circuits of data management unit 10 (e.g., stored in EEPROM 94 of FIGURE 3).

The arrangement shown and described relative to FIGURES 1-3 also is advantageous in that data relating to food intake, concurrent medication dosage and other conditions easily can be entered into the system and stored with the time and date tagged blood glucose test result for later review and analysis by the user and/or his or her healthcare professional. Specifically, a menu generated by the system at the beginning or end of the blood glucose monitoring sequence can include items such as "hypoglycemic" and "hyperglycemic," which can be selected using the switches of handheld microprocessor unit 12 (e.g., operation of control pad 30 and switch 36 in FIGURE 1) to indicate the user was experiencing hypoglycemic or hyperglycemic symptoms at the time

of monitoring blood glucose level. Food intake can be entered in terms of "Bread Exchange" units or other suitable terms by selecting a "food intake menu item and using a submenu display and the switches of handheld microprocessor 12 to select and enter the appropriate information. A similar menu item - submenu selection process also can be used to enter medication data such as the type of insulin used at the time of the glucose monitoring sequence and the dosage.

As was previously mentioned, program instructions stored in data management unit 10 and program instructions stored in program cartridge 42 of handheld microprocessor unit 12 enable the system to display statistical and trend information either in a graphic or alphanumeric format. As is the case relative to controlling other operational aspects of the system, menu screens are provided that allow the system user to select the information that is to be displayed. For example, in the previously discussed embodiments in which a system menu includes a "display" menu item, selection of the menu item results in the display of one or more submenus that list available display options. For example, in the currently preferred embodiments, the user can select graphic display of blood glucose test results over a specific period of time, such as one day, or a particular week. Such selection results in displays of the type shown in FIGURES 6 and 7, respectively. When blood glucose test results for a single day are displayed (FIGURE 6), the day of the week and date can be displayed along with a graphic representation of changes in blood glucose level between the times at which test results were obtained. In the display of FIGURE 6, small icons identify points on the graphic representation that correspond to the blood glucose test results (actual samples). Although not shown in FIGURE 6, coordinate values for blood glucose level and time of day can be displayed if desired. When the user chooses to display a weekly trend graph (FIGURE 7), the display generated by the system is similar to the display of a daily graph,

having the time period displayed in conjunction with a graph that consists of lines interconnecting points that correspond to the blood glucose test results.

The screen display shown in FIGURE 8 is representative of statistical data that can be determined by the system of FIGURE 1 (using conventional computation techniques) and displayed in alphanumeric format. More specifically, the exemplary screen display of FIGURE 8 provides statistical data for blood glucose levels over a period of time (e.g., one week) or, alternatively, for a specified number of monitoring tests. In the exemplary display of FIGURE 8, the system calculates and displays the average blood glucose level and the standard deviation. Displayed also is the number of blood glucose test results that were analyzed to obtain the average and the standard deviation; the number of test results under a predetermined level (50 milligrams per deciliter in the screen display shown in FIGURE 8); and the number of blood glucose tests that were conducted while the user was experiencing hypoglycemic symptoms. As previously noted, in the preferred embodiments of the invention, a screen display that is generated during the blood glucose monitoring sequence allows the user to identify the blood sample being tested as one taken while experiencing hyperglycemic or hypoglycemic symptoms and, in addition, allows the user to specify other relevant information such as food intake and medication information.

The currently preferred embodiments of the invention also allow the user to select a display menu item that enables the user to sequentially address, in chronological order, the record of each blood glucose test. As is indicated in FIGURE 9, each record presented to the system user includes the data and time at which the test was conducted, the blood glucose level, and any other information that the user provided. For example, the screen display of FIGURE 9 indicates that the user employed handheld microprocessor unit 12 as an interface to enter data indicating use of 12.5 units of regular

insulin; 13.2 units of "NPH" insulin; food intake of one bread exchange unit; and pre-meal hypoglycemic symptoms.

Use of data management unit 10 in conjunction with handheld microprocessor unit 12 also allows display of blood glucose test results along with food intake and/or medication information. For example, shown in FIGURE 10 is a daily graph in which blood glucose level is displayed in the manner described relative to FIGURE 6. Related food intake and medication dosage is indicated directly below contemporaneous blood glucose levels by vertical bar graphs.

It will be recognized by those skilled in the art that the above-described screen displays and system operation can readily be attained with conventional programming techniques of the type typically used in programming microprocessor arrangements. It also will be recognized by those skilled in the art that various other types of screen displays can be generated and, in addition, that numerous other changes can be made in the embodiments described herein without departing from the scope and the spirit of the invention.

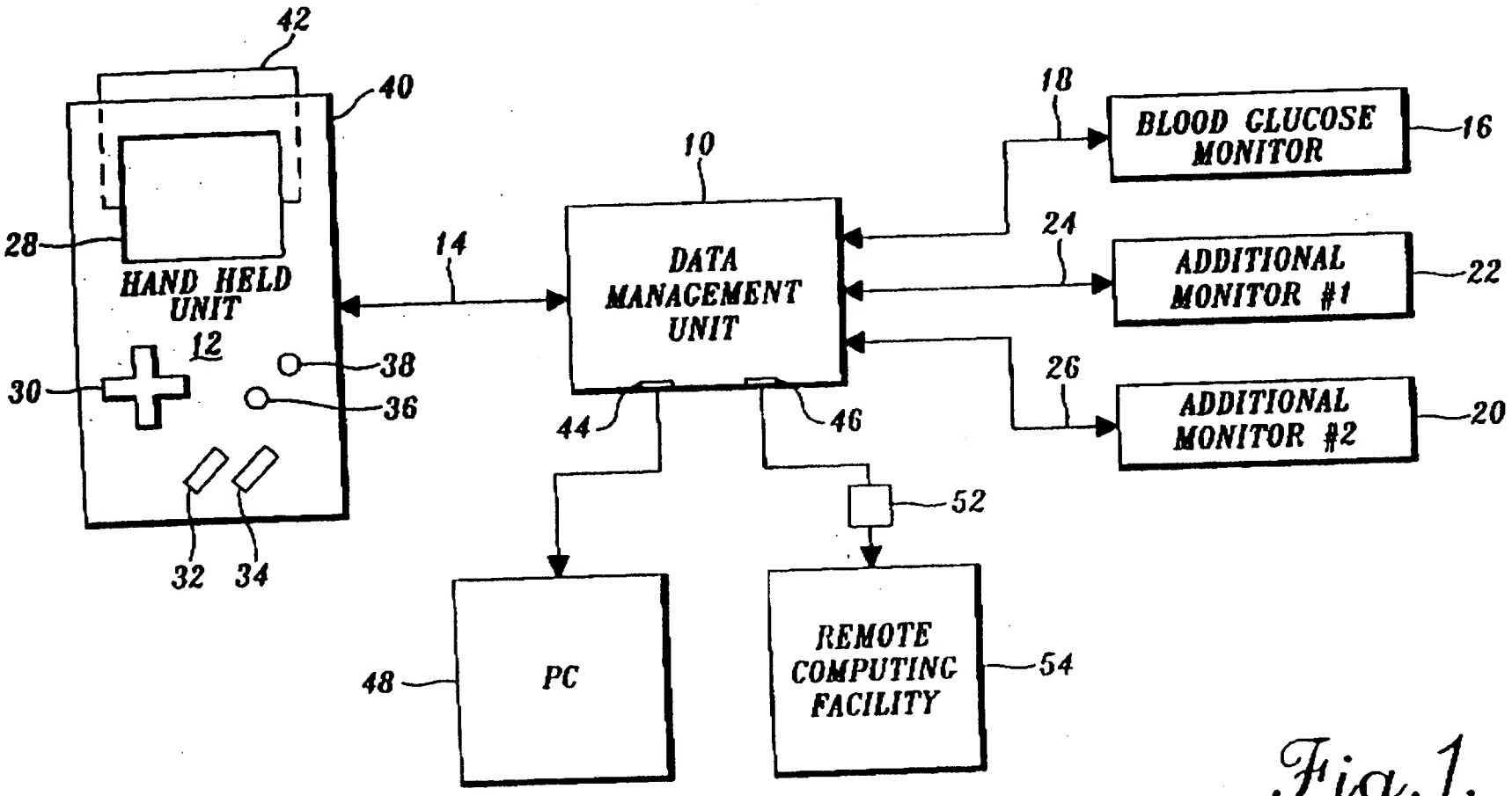

42
40
28
HAND HELD UNIT
12
30
38
36
32
34
14
10
DATA MANAGEMENT UNIT
44
46
18
BLOOD GLUCOSE MONITOR
16
24
ADDITIONAL MONITOR #1
22
26
ADDITIONAL MONITOR #2
20
52
48
PC
REMOTE COMPUTING FACILITY
54

Fig. 1.

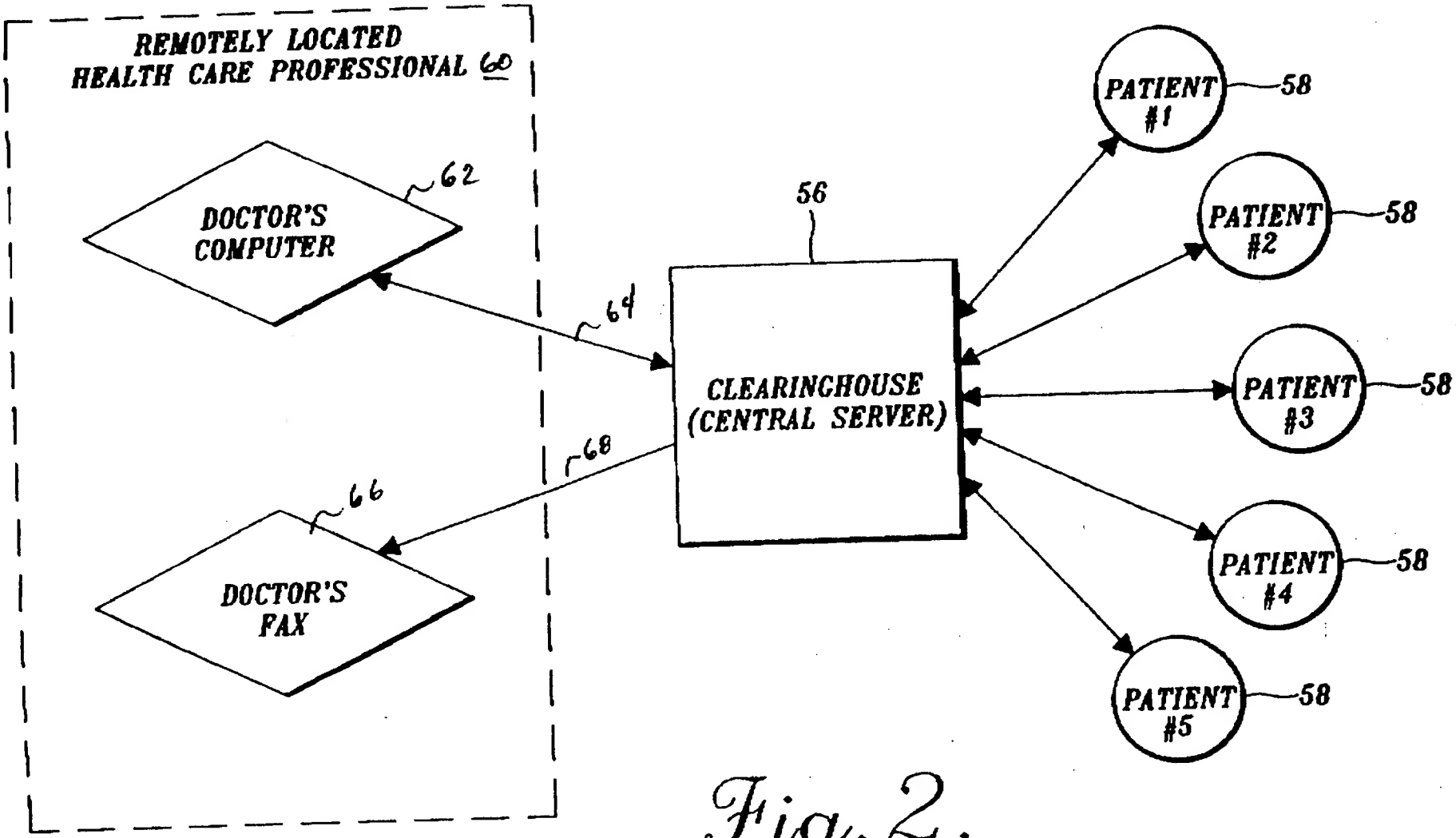

REMOTELY LOCATED
HEALTH CARE PROFESSIONAL 60
DOCTOR'S COMPUTER
62
64
DOCTOR'S FAX
66
68
56
CLEARINGHOUSE (CENTRAL SERVER)
PATIENT #1
PATIENT #2
PATIENT #3
PATIENT #4
PATIENT #5
58
58
58
58
58

Fig. 2.

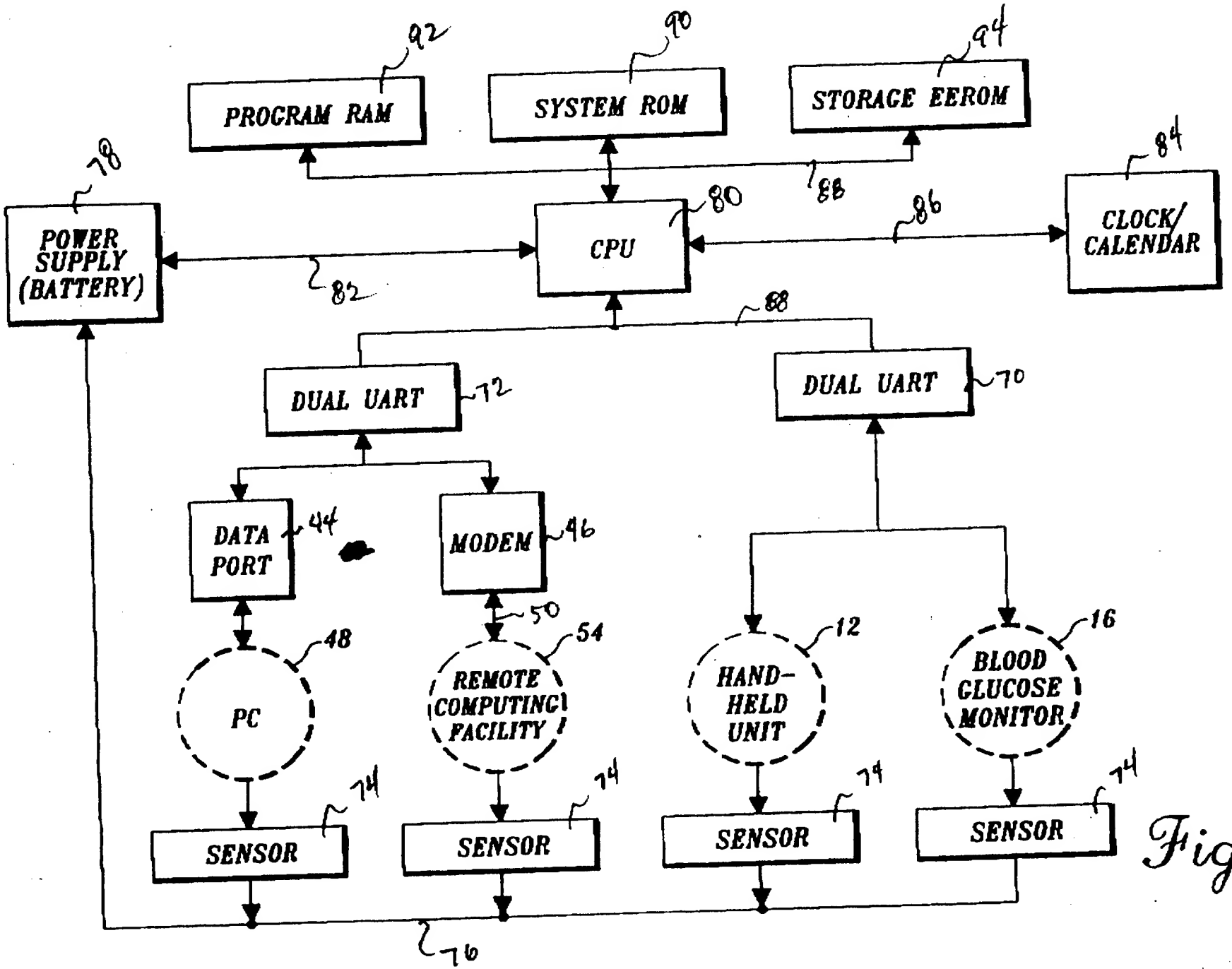

PROGRAM RAM
92
SYSTEM ROM
90
STORAGE EEROM
94
88
POWER SUPPLY (BATTERY)
78
CPU
80
CLOCK/ CALENDAR
84
86
82
88
DUAL UART
72
DUAL UART
70
DATA PORT
44
MODEM
46
50
PC
48
REMOTE COMPUTING FACILITY
54
HAND-HELD UNIT
12
BLOOD GLUCOSE MONITOR
16
SENSOR
74
SENSOR
74
SENSOR
74
SENSOR
74
76

Fig. 3.

Fig.4.

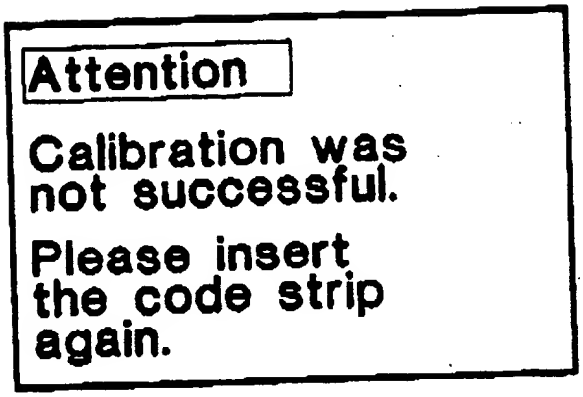


Fig.5.

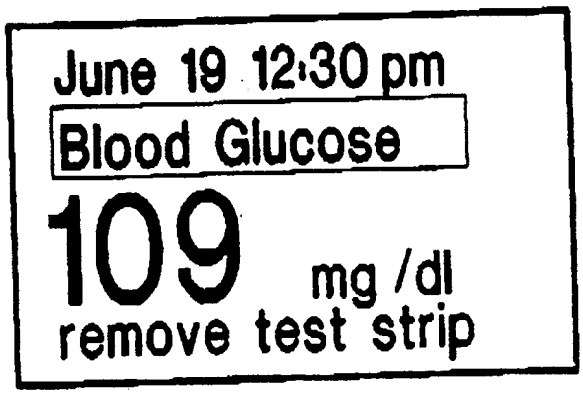


Fig.6.

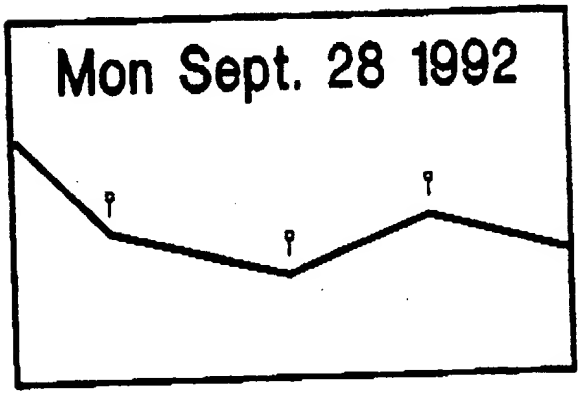


Fig.7.

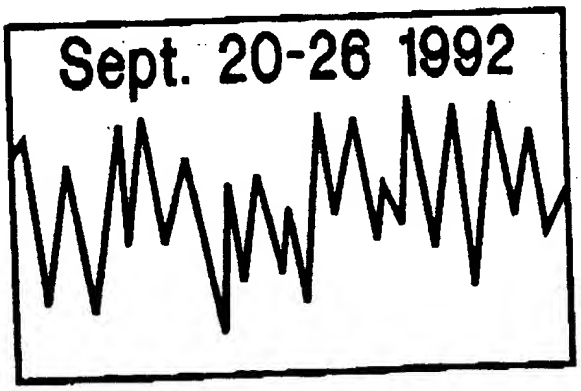


Fig. 8.

Glucose
Ave: 123 mg/dl
SD: 56
Num: 15
No. under 50: 13
No. hypo sym: 23

Fig. 9.

June 12 9:30pm

BG 113 mg/dl
Regin 12.5 U
NPHin 13.2 U
Food 1 BE
Pre-meal HYPO

Fig. 10.

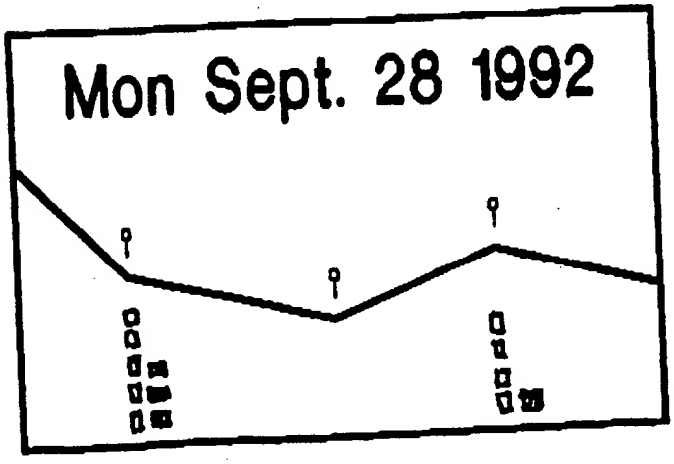


Exhibit 9

Facsimile Cover Sheet

To: Mr. James Anable Esq.
Company: Christiansen O'Connor
Phone: (206) 682-8100
Fax: (206) 224-0779

From: Steve Brown
Company: Raya Systems, Inc
Phone: (415) 949-3933
Fax: (415) 949-3935

Healthboy

Date: 10/02/92
Pages including this cover page: 3

Comments:

******* PANAFAX 155 *** -JOURNAL- ********** DATE 01/17/1900 ***** TIME 16:07 *********

NO.	COM	DOC	DURATION	X/R	IDENTIFICATION	DATE	TIME	DIAGNOSTIC
28	OK	03	00:01'35	XMT	GROUP3	01/17	16:05	020440AC0800

********** -PANASONIC- ********** - *********

October 2, 1992

Mr. James Anable Esq.
Christiansen O'Connor
2800 Pacific First Center
1420 Fifth Avenue
Seattle, WA 98101

Dear James:

I am faxing you the diagram which shows the basic system. I am worried about focusing on the particulars and losing the fundamentals, and I think this diagram needs to be in the application.

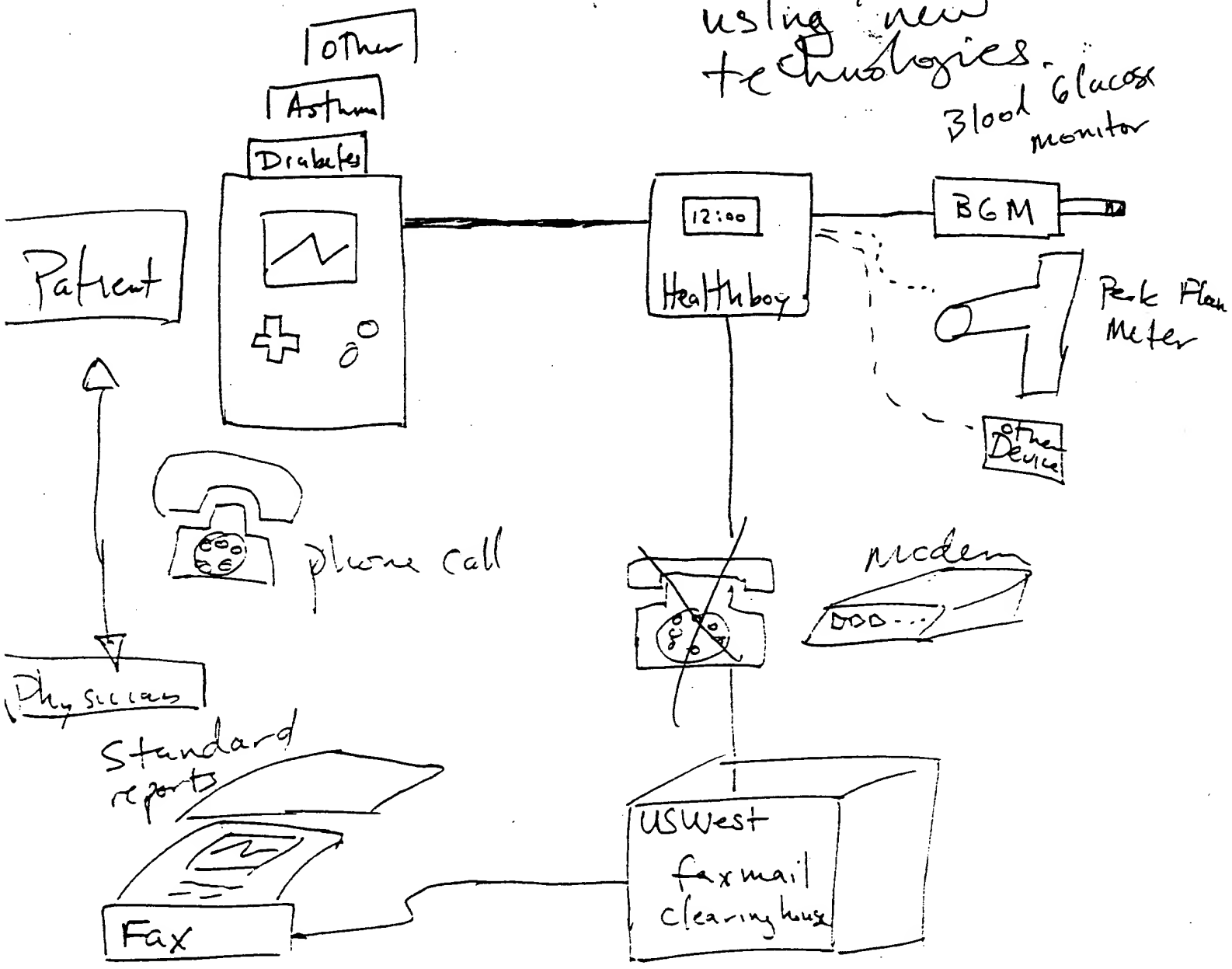
Sincerely,

Steve Brown
President

raya system

Raya Systems, Inc.
2570 West El Camino Real
Suite 309
Mountain View, CA 94040
phone: (415) 949-3933
fax: (415) 949-3935

The System — Link Juvenile Patients to Physicians using new technologies.



CHRISTENSEN, O'CONNOR,
JOHNSON & KINDNESS
2800 Pacific First Centre
1420 Fifth Avenue
Seattle, WA 98101
(206) 682-8100

RAYA SYSTEMS, INC. OCTOBER 31 1992
\
2570 WEST EL CAMINO REAL
SUITE 309
MT. VIEW, CA 94040

---

nvoice # 632084

or Services And Disbursements
**** RAYA-6631
1>MODULAR MICROPROCESSOR...
US PATENT APP

Services

OCT 01 92 JWA	Work on patent application	6.80		1,496.00
OCT 02 92 JWA	Review S. Brown comments regarding patent application draft; Review and revise patent application	1.40		308.00
OCT 07 92 JWA	Meeting with S. Brown; Work on patent application	4.90		1,078.00
OCT 27 92 JWA	Review and revise patent application	2.30		506.00
OCT 28 92 JWA	Review and revise patent application	1.50		330.00
OCT 29 92 JWA	Review and revise patent application	1.50		330.00
OCT 29 92 JM	Work on patent drawings	1.30		65.00
	Total Hours	19.70		
	Total Fees			4,113.00

Disbursements

OCT 19 92 FIRM	Telecopier handling charge	2.00	
	Photocopies	9.30	
	Long distance telephone charges	6.96	
	Total Disbursements		18.26

nable James W	JWA	PTNR	18.40	220.00	4,048.00	
lez Joel	JM	ILLU	1.30	50.00	65.00	
		ILLU	1.30	50.00	65.00	
		PTNR	18.40	220.00	4,048.00	

Disbursements

Continued

CHRISTENSEN, O'CONNOR,
JOHNSON & KINDNESS
2800 Pacific First Centre
1420 Fifth Avenue
Seattle, WA 98101
(206) 682-8100

RAYA SYSTEMS, INC. NOVEMBER 30 1992
\
2570 WEST EL CAMINO REAL
SUITE 309
MT. VIEW, CA 94040

---

nvoice # 636008

or Services And Disbursements
***** RAYA-6631
1>MODULAR MICROPROCESSOR...
US PATENT APP SN 977,323 11/17/92
BROWN SJ

Services

NOV 05 92 JM	Work on patent drawings	.40		20.00
NOV 17 92 JM	Work on patent drawings	.60		51.00
	Total Hours	1.00		
	Total Fees			71.00

Disbursements

NOV 11 92 FIRM	Telecopier handling charge	5.00	
	Long distance telephone charges	.47	
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lez Joel	JM	ILLU	1.00	71.00	71.00	
		ILLU	1.00	71.00	71.00	

Disbursements

	Long distance telephone charges	.47	
	Telecopier handling charge	5.00	
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	Total Fees		71.00
	Total Disbursements		5.47
			$76.47

nvoice due upon receipt. Interest charged at 1.50% per month from invoice date on amounts unpaid 45 days after invoice date.
hristensen, O'Connor, Johnson & Kindness--Tax I.D. No. 91-0860813
)005